Paper No. 12

# UNITED STATES PATENT AND TRADEMARK OFFICE

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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Ex parte NATESAN MURUGESAN, JOHN T. HUNT and PHILIP D. STEIN

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Appeal No. 2002-0522
Application No. 09/552,543

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

## DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 23, 24, 26, and 27. Claims 25 and 28 are also pending; the examiner has indicated that these claims would be allowable if rewritten in independent form. See Paper No. 3, mailed October 2, 2000, page 3.

Claim 23 is representative and reads as follows:

23. A pharmaceutical composition comprising at least one endothelin antagonist in combination with at least one additional therapeutic agent selected from ECE inhibitors, PAF antagonists, AII receptor antagonists, renin inhibitors, ACE inhibitors, NEP inhibitors, HMG CoA reductase inhibitors, squalene synthetase inhibitors, bile acid sequestrants, calcium channel blockers,

potassium channel activators, beta-adrenergic agents, antiarrhythmic agents, diuretics, and thrombolytic agents.

The examiner does not rely on any references.

Claims 23, 24, 26, and 27 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description in the specification.

We affirm.

Background

The specification discloses that "[c]ompounds of the formula I [chemical formula omitted] and pharmaceutically acceptable salts thereof are endothelin receptor antagonists useful, inter alia, as antihypertensive agents." Page 1. More specifically, "[t]he compounds of formula I are antagonists of ET-1, ET-2 and/or ET-3 and are useful in treatment of all endothelin-dependent disorders. They are thus useful as antihypertensive agents. By the administration of a composition having one (or a combination) of the compounds of this invention, the blood pressure of a hypertensive mammalian (e.g. human) host is reduced." Pages 8-9.

The specification also discloses that "[t]he compounds of the present invention are also useful in the treatment of" a variety of other disorders. See pages 9-10. "The compounds of this invention can also be formulated in combination with endothelin converting enzyme (ECE) inhibitors . . .; platelet activating factor (PAF) antagonists; angiotensin II (AII) receptor antagonists; renin inhibitors; angiotensin converting enzyme (ACE) inhibitors . . .; neutral endopeptidase (NEP) inhibitors; HMG CoA reductase inhibitors . . .; squalene

synthetase inhibitors; bile acid sequestrants . . .; calcium channel blockers; potassium channel activators; beta-adrenergic agents; antiarrhythmic agents; diuretics . . .; and thrombolytic agents." Page 10, lines 4-22. All of the original claims were directed to the compounds of formula I and methods of using these compounds.

Discussion

Claim 23 is directed to a pharmaceutical composition comprising "at least one endothelin antagonist" in combination with one of the therapeutic agents listed on page 10 of the specification.[1] Claim 23 is not limited to a composition comprising the endothelin antagonist of the specification's formula 1.

The examiner rejected the claims as lacking an adequate written description in the specification. The examiner noted that the

> specification only describes a pharmaceutical composition comprising an endothelin antagonist of the formula I in combination with at least one additional therapeutic agent. . . . The specification does not name or give the structure of what endothelin antagonists are contemplated except for the compounds of the formula I.

Examiner's Answer, page 4 (emphasis in original).

"The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1330, 65 USPQ2d 1385, 1397 (Fed. Cir. 2003). "In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for

[1] The claims stand or fall together. Appeal Brief, page 2. Therefore, claims 24, 26, and 27 stand or fall with claim 23.

the claimed subject matter at issue." Purdue Pharma L.P. v. Faulding, Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000). Nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. See id. "One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." Lockwood v. American Airlines Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997) (citation omitted, emphasis in original).

In this case, we agree with the examiner that the instant specification does not describe the composition of claim 23. The specification's disclosure with regard to endothelin antagonists is limited to those encompassed by formula I. At no point does the specification state or even suggest that the disclosed invention includes compositions comprising other endothelin antagonists. "It is not necessary that the application describe the claim limitations exactly . . ., but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented [the claimed invention] including those limitations." In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). The specification here does not describe the composition of claim 23 in terms that would lead persons of ordinary skill in the art to recognize that Appellants invented compositions including any endothelin antagonist, including endothelin antagonists not encompassed by formula I.

Appellants argue that "[t]he skilled artisan reading Applicant's [sic] parent specification would clearly and naturally understand that the disclosure at page 10, lines 4-34 is generally applicable to endothelin antagonists as an entire class—not just the specific endothelin antagonists of formula I." Appeal Brief, page 3. Appellants cite In re Smythe, 480 F.2d 1376, 178 USPQ 279 (CCPA 1973), as supporting their position.

This argument is not convincing. Again, the specification describes only compositions comprising the endothelin antagonists of formula I. Appellants have pointed to nothing in the specification that would have led those skilled in the art to conclude that Appellants invented compositions comprising endothelin antagonists other than those of formula I. See Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966 ("One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious.").

In re Smythe does not support Appellants' position. In Smythe, the specification disclosed a process comprising, inter alia, a "segmentizing medium" that was "air or other gas which is inert to [a] liquid." 480 F.2d at 1384, 178 USPQ at 280. The claimed process, by contrast, recited the segmentizing medium as "an inert fluid immiscible with said liquid samples." See id. The court reversed the rejection for inadequate written description, even though the claim term "fluid" was broader than the specification's "air or other gas," because "the specification clearly conveys to one skilled in the art that in this invention the

characteristics of a fluid are what make the segmentizing medium work in this invention." 480 F.2d at 1383, 178 USPQ at 284.

The Smythe court made clear that its conclusion was based on the specific facts of that case. See id. ("Each case must be decided on its own facts."). Smythe did not hold that disclosure of a species always provides a description of an encompassing genus. In fact, the Smythe court pointedly noted that the facts of that case were distinguished from

> other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, [where] one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application.

Id. at 1383, 178 USPQ at 284-285. This case falls squarely into the category of cases that the Smythe court distinguished. See, e.g., In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) ("In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.").

In fact, the Federal Circuit recently cited Smythe, along with Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993), as authority for the proposition that a "written description of a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559,

1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997) (bracketed material added by the Lilly court).

In this case, the specification provides no "precise definition" of the genus of endothelin antagonists recited in claim 23; as noted above, the specification does not even mention endothelin antagonists other than those of formula I. Therefore, the Federal Circuit's interpretation of Smythe supports the examiner's position in this case. The examiner's rejection is affirmed.

Summary

We agree with the examiner that the specification does not adequately describe the composition of claim 23. We therefore affirm the rejection under 35 U.S.C. § 112, first paragraph. Claims 24, 26, and 27 fall with claim 23.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

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| Sherman D. Winters<br>Administrative Patent Judge | ) |
| William F. Smith<br>Administrative Patent Judge | ) BOARD OF PATENT<br>) APPEALS AND<br>) INTERFERENCES |
| Eric Grimes<br>Administrative Patent Judge | ) |

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Marla J Mathias
Bristol- Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton NJ 08543-4000